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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,121	12/30/2003	Jeffrey O. Saunders	VPI/02-05 US	3285
27916	7590	02/06/2006	EXAMINER	
VERTEX PHARMACEUTICALS INC. 130 WAVERLY STREET CAMBRIDGE, MA 02139-4242			BARKER, MICHAEL P	
			ART UNIT	PAPER NUMBER

1626

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/749,121

Applicant(s)

SAUNDERS ET AL.

Examiner

Michael P. Barker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 6-9;10-13 (in part);14-24 (in part);25-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5;10-13 (in part);14-24 (in part) is/are rejected.
- 7) ☒ Claim(s) 6-9;10-13 (in part);14-24 (in part);25-74 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/16/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-74 are pending in this application. Group I, **Claims 1-5, 10-13** (in part), and **14-24** (in part), has been elected for prosecution. Group II, **Claims 6-9, 10-13** (in part), **14-24** (in part), and Group III, **Claims 25-74**, are withdrawn as being drawn to nonelected subject matter. Therefore, Group I has been examined on the merits for its patentability.

Information Disclosure Statement

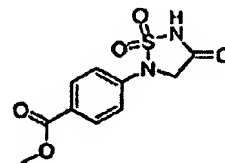
The information disclosure statement (IDS) submitted on September 16, 2005 was correctly filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please refer to Applicant's copy of the PTO-1449 submitted herewith.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Response to Election/Restriction

The restriction put forth November 15, 2005 is final, and **Claims 6-9, 10-13** (in part), **14-24** (in part), and **25-74** are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected subject matter, there being no allowable generic or linking claim. Applicant's election of Group I, **Claims 1-5, 10-13** (in part), and **14-24** (in part), as well



as the election to compound I-3 depicted in the Specification at p. 24, **I-3**, was made **without** traverse in the reply filed on December 7, 2005. The elected species was found to

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be free of the prior art, thus the search was expanded to include the entirety of Group I.

However, Group I was not found to be free of the prior art, giving rise to the rejections which follow.

Claim Rejections - 35 USC § 102(e)

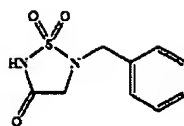
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Group I, **Claims 1-5, 10-13** (in part), and **14-24** (in part) rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Publication No.: US 20040023974 A1, published February 5, 2004, having a priority date of April 3, 2002 (hereinafter, "Coppola, et al."). Specifically, portions of Applicant's claimed genus, as described by Group I, are anticipated by certain exemplified embodiments as described in Coppola, et al. The following list is not exhaustive and does not include each and every species anticipating Applicant's broad genus. The first example lists the substituents used from Applicant's Group I which result in a species anticipated by a species exemplified by Coppola, et al.

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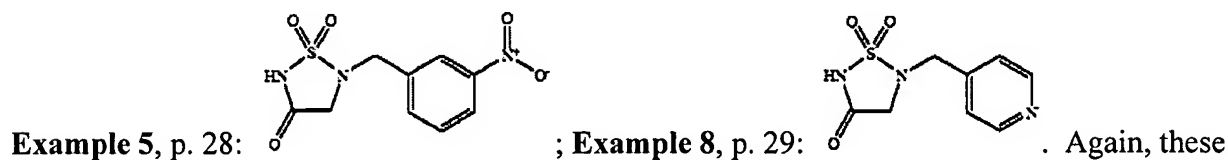
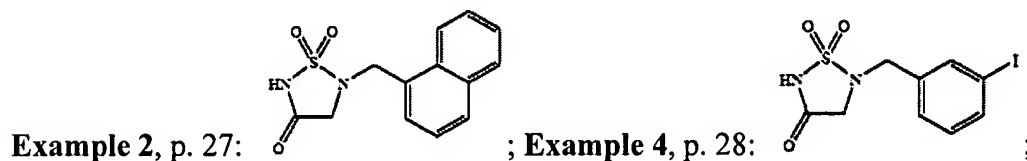


Coppola, et al. teaches the following compound, [Example 1, p. 27],

which anticipates Applicant's **Claims 1-5, 10-13** (in part), and **14-24** (in part), specifically wherein:

- **Q** is a C₆₋₁₀ aryl group;
- **T_m** is a C₁₋₆ alkylidene chain;
- **m** is one; and
- **X** is -CH₂-.

The subsequent examples do not explicitly typify the combination of substituents used to reach the specific species but can be created using Applicant's broad genus and thus form the basis of this 102(e) rejection. Coppola, et al. teaches the following compounds, all of which anticipate Applicant's **Claims 1-5, 10-13** (in part), and **14-24** (in part):



examples of anticipating species do not provide an exhaustive list of each and every anticipating species contained within Coppola, et al.

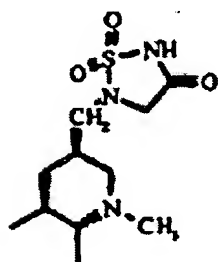
Claim Rejections - 35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(1) **Claims 1-5, 10-13 (in part), and 14-24 (in part)** are rejected under 35 U.S.C. 102(b) as being anticipated by Mantegani, et al., “Synthesis and Antihypersensitive Activity of 2,4-Dioxoimidazolidin-1-yl and Perhydro-2,4-Dioxopyrimidin-1-yl Ergoline Derivatives”, IL Farmaco, 53 (4): 293-304 (1998). Specifically, Mantegani, et al. teaches the sulfonyl derivative,



[Compound 6, Fig. 3, p. 296], which anticipates Applicant's instantly claimed

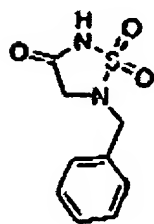
Group I wherein:

- Q is an optionally substituted heterocyclic group having 6 ring atoms;
- T_m is a C₁₋₆ alkylidene chain;
- m is one; and
- X is –CH₂–.

(2) **Claims 1-5, 10-13 (in part), and 14-24 (in part)** are rejected under 35 U.S.C. 102(b) as being anticipated by Albericio, et al., “Synthesis of a Sulfahydantoin Library”, J. Comb. Chem.

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2, 290-300 (May 2001). Specifically, Albericio, et al. teaches the sulfahydantoin,



[Figure 2, p. 292], which anticipates Applicant's instantly claimed Group I wherein:

- Q is a C₆₋₁₀ aryl group;
- T_m is a C₁₋₆ alkylidene chain;
- m is one; and
- X is -CH₂-.

Claim Rejections - 35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

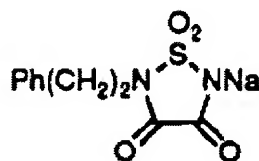
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Claims 1-5, 10-13 (in part), and 14-24 (in part) are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee, et al., "Intra- and Intermolecular α -Sulfamidoalkylation Reactions", J. Org. Chem. 55(25): 6098-6104 (1990).

Determining the scope and contents of the Prior Art



Lee, et al. teaches the following compound:

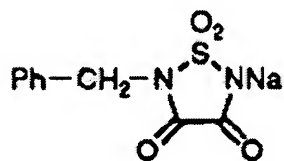
[Compound 34,

Scheme II, p. 6101].

Ascertaining the Differences Between the Prior Art and the Claims at Issue

(1) Homologous Series:

Applicant's instantly claimed invention, specifically wherein **Q** is a C₆₋₁₀ aryl group; **T_m** is a C₁₋₆ alkylidene chain; **m** is one; and **X** is -C(O)- and the disclosed compound of Lee, et al. differ only in that there is an additional CH₂ group attached to the ring-nitrogen in Lee's compound, whereas Applicant's claimed invention limits **m** to 0 or 1, resulting in the compound,



. The instantly claimed invention, then, is a homologue of Lee's specifically disclosed Compound 34.

Resolving the Level of Ordinary Skill in the Pertinent Art

(1) Homologous Series:

To those skilled in the chemical art, one homologue is not such an advance over adjacent members of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. *In re Henze*, 85 USPQ 261 (1950). The instantly claimed compounds would have been obvious to one skilled in the art because one skilled in the art would have been motivated to prepare homologues of the compounds taught in Lee et al. with the expectation of obtaining compounds of similar

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properties. Therefore, the instantly claimed compounds would have been suggested by Lee et al. to one skilled in the art.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 recites the limitation “depicted in Table 1”. There is insufficient antecedent basis for this limitation in the claim, as there is no mention in the Claims of a “Table 1”, rather, Applicant seems to be referring to the Specification. This rejection can be overcome by rewriting **Claim 5** to include those compounds listed in “Table 1”, though in doing so, the aforementioned rejections should be adhered to.

Objections

Group II, **Claims 6-9, 10-13** (in part), **14-24** (in part), and Group III, **Claims 25-74** are objected to for containing nonelected subject matter.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

When filing a FAX in Technology Center 1600, please indicate the Header (upper right) “Official” for papers that are to be entered into the file, and “ Unofficial” for draft documents

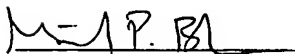
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and other communications with the PTO that are not for entry into the file of the application.

This will expedite processing of your papers.

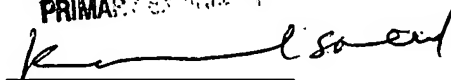
Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

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Michael P. Barker
Patent Examiner, AU 1626

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER



(for) Joseph McKane
Supervisory Patent Examiner, AU 1626